

REMARKS/ARGUMENTS

In response to the final Office Action dated May 3, 2006, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of pending claims 12-26, and pass this application to allowance.

Claims 12-26 have been newly rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over U.S. Patent No. 5,342,625 to Hauer et al. Hauer et al. has been cited for teaching cyclosporin pharmaceutical compositions in the form of micro-emulsion pre-concentrates that are filled in hard gelatin capsules. The abstract, examples, and column 29, lines 11-14 are specifically cited for this teaching.

With respect to the abstract, Applicants respectfully submit that the presently claimed invention is nowhere taught nor suggested. According to the abstract, the compositions of Hauer et al. typically comprise a C1-5 alkyl or tetrahydrofurfuryl di- or partial-ether of a low molecular weight mono- or poly-oxy-alkane diol, e.g., Transcutol or Glycofurol, as hydrophilic component. In contrast, the hydrophilic phase in the compositions of the present invention comprises a polyethylene glycol and at least one lower alkanol selected from ethanol and propylene glycol. According to the abstract of Hauer et al., the compositions also comprise a saccharide monoester, e.g., raffinose or saccharose monolaurate. The presently claimed hard gelatin capsules of the present application comprise no such saccharide monoester.

Column 29, lines 11-14, of Hauer et al., specifically cited by the Examiner, indicate that certain formulations (i.e., 5.2 and 5.3, listed there under), may be used for filling into size 1 or 2 hard gelatin capsules. In formulation 5.2, a partial-ether of a low molecular weight mono or poly-oxy-alkane diol, i.e., Transcutol is present, along with the polyoxyethylene-polyoxypropylene co-polymer Pluronic F68, sodium laurylsulphate and

sodium carboxymethylcellulose, none of which are comprised by the presently claimed pharmaceutical compositions. Moreover, both a surfactant comprising a reaction product of natural or hydrogenated vegetable oil and ethylene glycol and a hydrophilic phase comprising a polyethylene glycol and ethanol or propylene glycol, as presently claimed, are conspicuously absent from formulation 5.2 of Hauer et al.

Formulation 5.3 of Hauer et al. comprises the polyvinylpyrrolidone known as Kollidon, along with Transcutol, neither of which is not found in the presently claimed compositions. Moreover, a hydrophilic phase comprising a polyethylene glycol and either ethanol or propylene glycol, as presently claimed, is not present in formulation 5.3 of Hauer et al.

On page 2 of the Office Action, the Examiner has asserted that Examples 1, 4, 5 and columns 26-29 are directed to cyclosporin formulations which include the surfactant Labrafil M 1944 CS and Labrafil M 2130 (column 11), "both of which are described in the instant specification as reaction products of hydrogenated or natural vegetable oil and ethylene glycol." The Examiner's position is that Hauer et al. therefore teaches the claimed surfactant.

Both Labrafil M 1944 CS and Labrafil M2130 CS have HLB values of less than 10. See Table 5 of U.S. Patent No. 6,923,988, provided herewith as Exhibit A. In contrast, the present claims recite a surfactant having an HLB value of at least 10. Hauer et al. therefore does not teach or suggest a surfactant as recited in the present claims.

Hauer et al. has also been cited at column 18, final paragraph to column 19, first paragraph, for teaching "composition comprising propylene glycol and ethanol that read on the claimed lower alkanols." It is respectfully submitted that the passage which the Examiner has cited refers back to (A) and (B) of Hauer et al. Column 6 of Hauer et al. teaches that in addition to cyclosporin, the compositions of Hauer et al. (A) comprises:

(1) a hydrophilic phase; (2) a lipophilic phase; and (3) a surfactant. Compositions as defined under (B) of Hauer et al. comprise any components (1) to (3) listed above and water. See column 14, lines 4-7. Thus, Hauer et al. teaches that the hydrophilic phase in either (A) or (B) may be 1,2-propylene glycol. See column 18, lines 61. In contrast, the presently claimed invention comprising cyclosporin, and a hydrophilic phase comprising a polyethylene glycol and at least one lower alkanol selected from ethanol and propylene glycol, also comprises a surfactant of HLB value of at least 10 comprising a reaction product of natural or hydrogenated vegetable oil and ethylene glycol. The Examiner has not pointed to any portion of Hauer et al. that would suggest this specific combination.

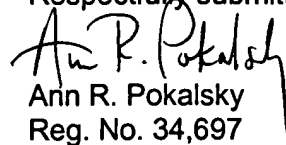
Since the Examiner has not pointed to any portion of Hauer et al. that would suggest the presently claimed invention, column 5, lines 57 through column 6, lines 35, do not “meet the claims 22, 23 and 26”, which depend from the main claim in the present application.

The Examiner readily admits that Hauer et al. “fails to specifically exemplify a combination of the claimed surfactants and lower alkanols.” Office Action page 2, final sentence to page 3, line 1. Applicants submit that not only does Hauer et al. fail to specifically *exemplify* the presently claimed invention, Hauer et al. also fail to suggest the presently claimed compositions or motivate one skilled in the art to make such compositions.

Applicants respectfully submit that the Examiner has selected various bits and pieces of the compositions taught by Hauer et al., and used such information to find the present claims obvious. In so doing, the Examiner has relied on the considerable benefit of hindsight reconstruction, which is never proper in making an obviousness determination.

Accordingly, in view of the foregoing comments, Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 12-26 under 35 U.S.C. §103(a) and pass this application to issue.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Ann R. Pokalsky". The signature is stylized with a large, looped initial "A" and a long, sweeping underline.

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